



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office
m2377n
297 Plus Park Boulevard
Nashville, TN 37217

February 10, 1999

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Southern Fish & Oyster Co., Inc.
PO Box 307
Mobile, AL 36601

ATTN: Ralph L. Atkins, Jr.
President/Owner

WARNING LETTER No. 99-NSV-05

Dear Mr. Atkins:

An inspection of your seafood processing plant by FDA Investigator David R. Heiar on September 24-25, 1998, found continuing and serious deviations from the requirements set forth in Title 21, Code of Federal Regulations, parts 110 and 123. By virtue of the noted deficiencies in your seafood processing operations, the products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act.

During our inspection, our investigator documented the following HACCP deviations:

- Failure to have or implement HACCP plans for seafood products which you process, according to requirements in Part 123.6(b). Your firm has no plan for scombroid species, which they process and distribute. Your firm appears to require that all amberjack be received fully iced. However, this is not adequately monitored. There are no recorded observations of ice, or rejections of product that is not iced. Icing is only part of the control that would be needed at receipt or as a backup during storage to control/prevent histamine formation.

One control strategy your firm could use at receipt would be to check for ice or to obtain transportation temperature control records, and take the internal temperature of the product. A second strategy would include analyses of samples of the incoming product showing less than 50 parts per million (ppm) histamine, coupled with sensory examinations showing less than 2.5% decomposition. Also, the product would have to be fully iced and have an appropriate internal temperature--depending on the time of death of the fish. (See the Guide, pg. 75.)

In addition, the investigator observed that your firm does not follow the plan it has for crab

or shrimp in that they it does not monitor CCP critical limits (CLs) adequately or record its observations.

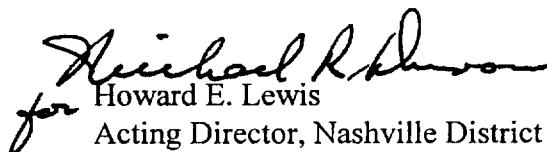
- Failure to identify or control safety hazards that are reasonably likely to occur, as required in Part 123.6(b) and (c)(1). For example, histamine is a likely hazard that should be controlled in scombroid fish, such as amberjack and tuna; sulfites are reasonably likely to occur in fresh or frozen shrimp; and, the processing of fresh crabmeat requires controls to prevent pathogen growth.
- Failure to monitor and maintain sanitation monitoring records that are required by Part 123.11, including failure to sanitize equipment, to follow appropriate personal hygiene practices, to maintain cooling equipment to prevent temperature abuse, to remove the potential for cross-contamination in cooler and freezer storage, and to take measures that control pests.

At the termination of the inspection, Investigator Heiar issued you a written list of objectionable conditions and discussed them with you. You should take prompt action to correct these noted violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

Please notify this office in writing within 15 working days after receipt of this letter of the specific steps you have taken to correct the noted violations and prevent the recurrence of any similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be made.

Your reply should be directed to the attention of Frank J. Jancarek, Compliance Officer, at the above letterhead address.

Sincerely,


for Howard E. Lewis
Acting Director, Nashville District

HEL:man